90-225

Supreme Court, U.S.
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No. 90-

IN THE

Supreme Court of the United States

OCTOBER TERM, 1990

SEKOU EALY, infant, by ROBERT EALY and SANDRA EALY, guardians,

Petitioners,

v.

RICHARDSON-MERRELL, INC.,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Should a single federal circuit, in conflict with the position taken by nine other circuits, be allowed to use Fed. R. Evid. 703 — which permits experts to testify on the basis of information not itself admitted into evidence, provided this information is "reasonably relied upon" in practice by experts in the field — as a means of withholding from federal trial juries in that circuit expert opinions that are concededly based on *information* reasonably relied upon by such experts, simply because the circuit court has decided that *the expert opinions themselves*, given the weight of the other side's expert opinion testimony, are not "reasonable"?

2. Where a federal district court, applying Fed. R. Evid. 104(a), admits expert opinion testimony after finding (on uncontested evidence) under Rule 703 that the information on which the testimony is based is information "reasonably relied upon" in the field, should a court of appeals be permitted to overturn that finding by employing a *de novo* analysis that looks beyond the record, by deeming the issue of admissibility "a matter of law," where all other circuits deem the identical Rule 703 issue to involve a factual finding entitled to appellate deference?

3. Should a federal circuit court, in conflict with the position taken by two other circuits, be allowed to grant judgment n.o.v. rather than awarding at most a new trial when it concludes that the record, "as abridged" to exclude evidence the circuit court believes was erroneously admitted, would not have supported the verdict — despite the conceded fact that the evidence actually *admitted* at trial *did* support that verdict?

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OPINIONS BELOW

The opinion of the United States Court of Appeals for the District of Columbia Circuit, reversing the District Court's denial of judgment n.o.v., is reported at 897 F.2d 1159 and reprinted as Appendix A, at page A1.[1] The opinion of the United States District Court for the District of Columbia, from which appeal was taken, is unreported and reprinted as Appendix B, at page A13.

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[1] References to the appendices bound with this Petition are styled "A ___". References to the district court transcript included in the record below are styled "Tr. ___".

JURISDICTION

The opinion of the court of appeals was announced on March 9, 1990. A timely petition for rehearing and suggestion for rehearing *en banc* was denied on May 3, 1990. See Appendix C, at page A24. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTES AND RULE INVOLVED

Rule 703 of the Federal Rules of Evidence, which were enacted by Congress as a statute in 1975, provides:

> **Rule 703. Bases of Opinion Testimony By Experts**
>
> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

Rule 104(a) of the Federal Rules of Evidence provides:

> **Rule 104. Preliminary Questions**
>
> **(a) Questions of admissibility generally.** Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination it is not bound by the rules of evidence except those with respect to privileges.

Rule 50(b) of the Federal Rules of Civil Procedure provides in relevant part:

> **Rule 50. Motion for a Directed Verdict**
>
> **(b) Motion for Judgment Notwithstanding the Verdict.** . . . Not later than 10 days after entry of judgment, a party who has moved for a directed verdict may move to have the verdict and any judgment entered thereon set aside and to have judgment entered in accordance with his motion for a directed verdict . . . . A motion for a new trial may be joined with this motion, or a new trial may be prayed for in the alternative. If a verdict was returned the court may allow the judgment to stand or may reopen the judgment and either order a new trial or direct the entry as if the requested verdict has been directed.

STATEMENT OF THE CASE

1. Summary

At trial below, petitioners won a substantial personal injury jury verdict, supported by expert opinion testimony on the causation issue. The experts testified — without contradiction — that the types of information they relied upon for their opinions are normally and routinely relied on in their fields, outside of court, in evaluating similar causation questions, and that it is reasonable to rely on this information in forming conclusions. The district judge, pursuant to Rule 703, accordingly lifted from the experts the need to introduce into evidence *all* the information on which they had relied, and to limit their opinions *only* to that material. The district judge ruled, following the jury verdict, that on the evidence presented reasonable jurors could fairly rule either way, and denied the motion for judgment n.o.v.

The ruling and reasoning of the court of appeals in reversing the district judge and requiring entry of judgment n.o.v. illustrates, and exacerbates, three longstanding and serious conflicts among the circuits over basic and recurring principles of federal evidence law. The court's holding also conflicts with important principles laid out in past decisions of this Court.

First, the court of appeals ruled that, in determining under Rule 703 whether the type of unadmitted information used by an expert witness is "reasonably relied upon" in the relevant field, the issue: (1) is *not* whether experts in the field deem it reasonable to rely on this information, and normally do so in practice (which is all the First, Third, Fourth, Sixth, Seventh and Eighth Circuits require); and (2) is *not* whether the type of information involved, in general, seems reliable to the court (as the Second, Fifth and Tenth Circuits require in addition); but (3) is simply whether the appellate court regards the expert's *ultimate opinion* as *itself* unreasonable, given the weight of the other side's expert opinion testimony. The court below analyzed neither the language nor the history of Rule 703, even though it was interpreting an Act of Congress. The court's decision adds further confusion to an already intractable, multi-Circuit split, dating to 1983, and concerning an enactment of Congress specifically designed to provide a nationally uniform rule of procedure — an enactment relevant to virtually *every* federal trial involving expert testimony.

Second, the court of appeals accorded no deference whatever to the district judge's decision to admit petitioners' expert opinion testimony, subjecting it to a *de novo* analysis on the theory that it was "a matter of law". The court pointed to nothing in Rule 104(a) or Rule 703 authorizing this result. It ignored this Court's holding in *Salem* v. *United States Lines Co.*, 370 U.S. 31, 35 (1962), that, in general, "the trial judge has broad discretion in the matter of the admission or exclusion

of expert evidence, and his action is to be sustained unless manifestly erroneous." And it rejected the holdings of the other eleven circuits, which all require at least *some* level of deference to Rule 703 determinations by the district court.

Third, the court of appeals entered judgment n.o.v. *without a finding that the evidence considered by the jury failed to support the verdict reached.* Rather, the appellate court first ruled that petitioners' expert opinion testimony had been erroneously admitted under Rule 703. The court then created a "phantom" record by deleting this evidence. Ignoring the distinct possibility that the Ealys had relied on the trial court's admission of their expert testimony in declining to burden the trial with other, seemingly duplicative evidence, the appellate court decided that the phantom it had called up was the record the jury would have considered if no evidentiary errors had occurred. Finally, the appeals court concluded that the jury's verdict could not be supported on that phantom record, and then entered judgment n.o.v.

In proceeding in this hypothetical manner, the court of appeals ignored the basic nature of a motion for judgment "notwithstanding the verdict". The whole point of such a motion is to determine whether the jury clearly erred in rendering the judgment it did *on the evidence presented.* Evidentiary rulings are obviously "not appropriate to be considered in connection with [a] motion for judgment." *Montgomery Ward & Co.* v. *Duncan,* 311 U.S. 243, 249 (1940). The court of appeals not only ignored this basic principle but also cavalierly disregarded the unfairness inherent in treating the petitioners as though they had not reasonably *relied* on the challenged evidentiary rulings in deciding not to offer into evidence *all* the data on which their experts depended on, once the trial court had allowed them under Rule 703 to streamline the trial by simply referring to matters "reasonably relied upon" in the field. Thus the court of appeals, by proceeding in a way that two other cir-

cuits have expressly declined to adopt, erred in assuming that the phantom record it had constructed is the record that would have existed if the trial court had made an opposite evidentiary ruling. Indeed, it is precisely to protect such reliance that the Fifth and Eighth Circuits have flatly barred the phantom record tactic relied on by the court of appeals below. The court below has rejected the position of those two circuits.

Finally, this case is peculiarly suited to the exercise of this Court's supervisory power over the lower federal courts. For the decision below poses separation-of-powers problems serious enough to undermine the integrity of the Judiciary, and it would be beneficial for this Court to address those issues before other circuits are induced to repeat the D.C. Circuit's error.

2. Procedural and Factual History

Very little of the trial record need be set forth in order to pinpoint the legal issues that warrant review by this Court. The following explication of the types of information relied upon by the experts at trial, and of the testimony about the reasonableness of relying on these types of information, is provided simply to enable the Court to satisfy itself that the questions on which petitioners seek review are ones on which conflicts of substance exist — that the result in this case would clearly have been different under the law of other Circuits.

Petitioner Sekou Ealy was born with severe, crippling limb deformities. (A3, A17 to A19). His mother took the anti-nausea drug Bendectin for morning sickness during her pregnancy (A3). On behalf of Sekou, his parents sued the drug's manufacturer, Richardson-Merrell, Inc. ("Merrell") on a variety of tort and contract grounds.[2]

[2] That company is now succeeded in interest by Merrell Dow Pharmaceuticals, Inc.

The case boiled down to the issue of whether the Bendectin had caused Sekou's birth defects. As the trial court noted, both sides "presented substantial conflicting evidence on the issue of causation." (A16). Scientific data concerning the issue was admitted into evidence, and experts on both sides expressed their opinions about causation based both on this evidence and on data not admitted into evidence but which they testified — without contradiction — was "reasonably relied upon" in their respective fields, and of which the trial judge approved under Rule 703.

It was uncontested that Mrs. Ealy took the Bendectin during the critical period when Sekou's limbs were forming, and the Ealys' experts focused on scientific evidence analyzing the specific mechanism through which they testified that Bendectin, by stunting cell development, causes limb deformities during this critical period of gestation. The experts testified that the chemical structure of Bendectin reveals that it crosses the placental barrier and can cause defects. Direct experimentation on human fetuses is of course ethically barred, so the experts relied for direct evidence on the standard substitutes: controlled scientific experiments subjecting various animal species to dosages of Bendectin during fetal formation (*in vivo* studies), and test-tube (*in vitro*) studies involving microscopic examination of animal cells subjected to Bendectin while in the process of cell division.

The Ealys also put on expert testimony assessing the relevance and meaning of epidemiological data from four studies presented by the defense. These studies compared groups of women who had taken Bendectin with groups who had not, and reported the incidence of limb deformities in babies for each group in an effort to determine a correlation. The Ealys' main epidemiology expert testified that these studies were of limited usefulness — because of the indirect and uncontrolled nature of the observational technique, the small size of the

available population groups, and the lack of any proof that any of the women had taken Bendectin during the critical period of limb formation — but testified that, inasmuch as the data from these studies indicated a substantially higher rate of birth defects among women taking Bendectin, the studies as a whole tended to show that Bendectin is a cause of limb deformities.

Based on all four types of data — and in light of the fact that nothing in the Ealys' genetic background, environmental influences, or health habits suggested another risk factor — the Ealys' experts testified to a reasonable degree of medical certainty that Bendectin had, in fact, caused Sekou's injuries. The district judge admitted all the opinions under Rule 702 on the basis that those opinions came from qualified experts providing evidence helpful to the jury and, as to the out-of-record data, on the basis that the data met the Rule 703 requirement that they are "reasonably relied upon" by experts in the field in assessing whether or not chemicals cause birth defects.

Merrell mounted a vigorous defense with ample expert testimony of its own. Its experts relied for their opinions on the same four types of data (and the opinions were similarly admitted under Rules 702 and 703), but they reached conclusions from that data that were contrary to the conclusions of the Ealys' experts. Merrell's experts argued that the studies of chemical structure were ultimately inconclusive. And as to particular *in vivo* and *in vitro* studies on animals, the defense experts also voiced a variety of criticisms.

Merrell's chief argument, however, was that animal studies are not actually performed on humans, that animals are different from humans, and that therefore epidemiological studies — which involve observation of actual human populations, even though they are not controlled experiments — represent a *better* form of data about the possible effects of Bendectin. Despite the fact that the actual data from the four studies the

defendants introduced concerning limb deformities[3] showed substantially more deformities in children whose mothers had taken Bendectin, Merrell's experts testified at length that these very studies constituted affirmative proof that Bendectin did *not* cause limb deformities.

Their explanation was that, given the danger that observed differences in the rate of deformities among Bendectin and non-Bendectin mothers might be a result of chance, no epidemiologist would conclude that there was a "statistically significant" difference unless he or she were *95% certain* that a correlation existed. Because all four studies fell short of this level of certainty, they testified, an epidemiologist would conclude that the studies fail to show *any* relationship between Bendectin and birth defects. And, because the only human data failed — as interpreted under this proof standard — to show causation, the defense urged the jury to conclude that the studies affirmatively indicated that Bendectin *did not* cause birth defects. The Ealys' experts vigorously contested the validity of that scientific reasoning.

Throughout the trial, it was uncontested that all four types of information from which both sets of experts were forming opinions are normally and reasonably relied upon by competent researchers attempting to determine whether particular chemicals cause particular birth defects. The testimony of the Ealys' experts to that effect (reprinted at A28 to A33) was uncontradicted; at most, Merrell's experts suggested that there were limits to the usefulness of animal studies and that, in their opinion, epidemiological studies were more helpful. In fact, Merrell's experts testified that they specifically rely on animal

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[3] Although other Bendectin trials, like the *Richardson* trial, see *infra* pp. 11-12, have litigated the meaning and value of thirty or more epidemiological studies of Bendectin, in this case the defense filed a motion *in limine* barring use of any other studies, which the district court granted, and the parties focused on these four epidemiological studies concerning limb defects alone.

studies in forming conclusions about whether Bendectin causes birth defects.[4] Also uncontradicted was the testimony of the Ealys' epidemiology expert that it would be unimaginable in this field *not* to consider *all* available chemical structure and animal studies. She stated that she could not "think of any situation where you would only rely on epidemiology" data "in the course of" work in the field, in determining whether chemicals cause birth defects (A32), and that this "is the commonly held view by epidemiologists" (A33); this testimony was also uncontradicted.[5]

The trial court accordingly allowed the case to go to the jury, which returned a verdict in favor of petitioners on the issue of liability, and awarded substantial damages. (A2, A13). Merrell moved for judgment n.o.v. The district court, "[a]fter a careful review of the entire record," concluded: "Viewing all the evidence and the reasonable inferences therefrom in the light most favorable to the plaintiffs, the Court finds that fair-minded people could differ as to the conclusion drawn by the jury on the issue of liability in this case." (A15 to A16). It therefore denied the motion. (A23). It also denied Merrell's motion for a new trial. (A16, A23).

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[4] One Merrell witness acknowledged that animal studies "are important to look at" (A33) in assessing possible mechanisms by which a drug could harm a fetus, although she expressed her opinion that she was "unable to find any suggested mechanism in [the Ealys'] animal studies" (A33). Another, when asked, "You do rely on each of these [animal studies] in part to draw an inference that Bendectin will not harm the human fetus?," answered "Yes". (A34).

[5] Nowhere did Merrell's experts suggest that a competent researcher attempting to determine whether a chemical causes birth defects would exclude other sources of information and rely *solely* on epidemiological data. They stated only that, in their opinion, "epidemiologic studies are the most accurate in terms of what is happening in humans" (A34) and that "epidemiologic studies represent the best source of information as to whether or not birth defects are associated with the drug." (A35).

3. The Intervening *Richardson* Decision

Subsequent to the district court's ruling, the court of appeals handed down an opinion in another case alleging harms from Bendectin, *Richardson* v. *Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S.Ct. 218 (1989), in which it held that a trial judge had not erred in excluding expert testimony under Rule 703. The petition for certiorari in that case, which this Court denied, was highly fact specific and stressed the effect of the trial court's action in undermining local substantive law and in diminishing access to trial by jury.

Richardson was the reference point of the opinion of the court of appeals below in this case. There, the district court had granted judgment n.o.v. in favor of Merrell, finding that plaintiffs' expert opinions lacked "a genuine basis 'in or out of the record' ". *Id.* at 829 (citations omitted). The court of appeals in *Richardson* interpreted that as a finding that the requirements of Rule 703 had not been met, and upheld the grant of judgment n.o.v. on the ground that it agreed with the implicit Rule 703 determination and, inasmuch as the question of adequate basis was an "issue[e] of law falling within the province of the court," the function of the jury was not being usurped. *Id.* at 833.[6]

The *Richardson* court opined that, in making a Rule 703 determination, a court must "look behind [an expert's] ultimate conclusion . . . and analyze the adequacy of its foundation." *Id.* at 829. The court opined that this involves not an assessment of whether experts rely on certain types of information in practice and whether it is generally reasonable to do so, but rather an assessment of the court's view of the *weight of the opinion* derived from this information, compared with the weight

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[6] *See also id.* at 829 ("Whether an expert's opinion has an adequate basis, and whether without it an evidentiary burden has been met, are matters of law for the court to decide.").

of contrary opinion on the other side. The *Richardson* court's conclusion was that the large number of epidemiological studies that failed to show a "statistically significant" association between Bendectin and birth defects — that is, a 95% certainty that a positive correlation in fact exists, *id.* at 831 — simply outweighed the other information relied on by the plaintiffs' experts and therefore the foundation could not be adequate. *Id.* at 830, 832.[7]

4. The Decision Below

On appeal in this case, Merrell argued "that the *Richardson* decision provides a binding legal precedent that requires reversal of the trial court's denial of its motion for judgment n.o.v." (A5). The Ealys responded that *Richardson* had simply ruled that the district court had not erred, *on that record*, in excluding evidence under Rule 703. They argued that the decision of the district judge in their case was entitled to deference and should be evaluated *on their record*, not on a record made in another case, in which they were neither actually nor virtually represented. *See also supra*, page 9, note 3.

The court of appeals necessarily agreed that *Richardson* could not dispose of this case as a matter of *res judicata*,[8] but

[7] The court explained: "These three types of studies then — chemical, *in vitro*, and *in vivo* — cannot furnish a sufficient foundation for a conclusion that Bendectin caused the birth defects at issue in this case," because "[s]tudies of this kind, singly or in combination, are not capable of proving causation in human beings in the face of the overwhelming body of contradictory epidemiological evidence." 857 F.2d at 830. It concluded that Bendectin "has been extensively studied and a wealth of published epidemiological data has been amassed, none of which has concluded that the drug is teratogenic. Uniquely to this case, the law now has the benefit of twenty years of scientific study, and the published results must be given their just due."

[8] In an opinion issued on the same day it decided this case, *Herring* v. *Merrell Dow Pharmaceuticals Inc.*, 897 F.2d 1383, 1383 n.1 (D.C. Cir. 1990), the court of appeals indicated that, although *Richardson* had "precedential effect" it "could not have had a *res judicata* effect on the *Herring* case because the plaintiffs in the two cases were different. *Montana* v. *United States*, 440 U.S. 147, 153 (1979)."

nonetheless announced that *Richardson* would henceforth be treated as articulating a "binding legal rule," applicable to *all* cases, that "an expert opinion that Bendectin is a human teratogen which caused the plaintiff's birth defects is without scientific foundation under Federal Rule of Evidence 703 in the face of 'a wealth of published epidemiological data' to the contrary. 857 F.2d at 832." (A3). As the court further elaborated:

> The *Richardson* court concluded, as a matter of law, that the "wealth of published epidemiological data . . . none of which has concluded that the drug is teratogenic . . . must be given their just due." 857 F.2d at 832. Therefore, under Rule 703, an opinion refuting this scientific consensus is inadmissible for lack of an adequate foundation, in the absence of other substantial probative evidence on which to base this opinion. It is this uncontroversial rule of evidence that is the *ratio decidendi* of *Richardson* and this case.

(A8).

In extracting from *Richardson* this quite surprising new federal rule of evidence, the court below observed: "Because *Richardson* provides a binding legal precedent governing the admissibility of expert opinion on the ability of Bendectin to cause human birth defects, the Ealys can only avoid that decision by showing that the record here is materially different from *Richardson*." (A9). The court found no such difference, given that most of the studies relied on by the Ealys' experts were "virtually the same" as *Richardson* and that the *new* data presented had "dubious significance in the face of the epidemiological data." (A9). As to the Ealys' focus "on specific statements made by various experts on both sides that were not made in *Richardson*"— the statements indicating the ex-

perts' agreement that all four types of data are "reasonably relied upon" by experts in the field (see A27 to A35) — the court found these not "material" because, "[a]ccording to *Richardson*, none of the evidence relied upon by the Ealys' experts . . . provides an adequate scientific foundation" (A10). Nor did the court afford any deference to the decision of the district judge, in light of the experts' agreement, to admit these opinions under Rule 703.

The court also decreed that, for all future cases, until stronger "new epidemiological or other types of data" is generated by scientific research, the large number of published epidemiological studies all failing to indicate with 95% certainty that Bendectin causes birth defects "must be recognized as the measuring stick for the admissibility of expert testimony on this issue." (A11 to A12).

Thus the court below, starting with *Richardson*'s relatively modest and case-specific ruling that it was not error for the trial judge to have excluded expert opinion testimony on the record "in this case," *supra* page 12, note 7, has essentially *enacted* an evidentiary rule that permits it to force the exclusion of evidence in any *type* of case where the appellate court believes that expert opinions reaching one set of conclusions are sufficiently outweighed by expert opinions on the other side.

5. The Refusal to Limit the Relief For Any Evidentiary Errors to Granting Merrell's Motion for a New Trial

Finally, although the relief from evidentiary errors that Merrell had requested of the court of appeals had been limited to a grant of a new trial, the court of appeals *sua sponte* ordered a grant of judgment n.o.v. based on the evidence that remained *after* its evidentiary analysis. It observed that, "[u]nfortunately for the Ealys, the only evidence they have on the issue of scientific causation is the testimony of their experts. Once that

testimony is deemed inadmissible, it is self-evident that the evidence is insufficient to support a verdict for the plaintiffs." (A11).

6. The Petition for Rehearing

Because the court of appeals' bootstrapping of the *Richardson* decision into this new, circuit-wide evidentiary doctrine raised novel issues that petitioners could not fairly have anticipated, they petitioned for rehearing and suggested rehearing *en banc*, identifying the dramatic departure of this court of appeals from the settled approach of other circuits. That petition was denied. (A24).

REASONS FOR GRANTING THE WRIT

1. This Court should resolve the important issue of the proper statutory interpretation of Federal Rule of Evidence 703 — an issue on which the circuits are in sharp and longstanding conflict.

There is a clear, persistent and important conflict in the circuits over the construction of Rule 703. The conflict as it existed even prior to the court of appeals decision below is best illustrated by the most noted case on the issue, *In Re Japanese Electronic Products Antitrust Litigation*, 723 F.2d 238 (3rd Cir. 1983), *rev'd on other grounds sub nom. Matsushita Elec. Indus. Co.* v. *Zenith Radio Corp.*, 475 U.S. 574 (1986). There, the district court refused to admit into evidence expert antitrust reports, or live opinions concerning them, despite uncontradicted affidavits establishing that the data in them were reasonably relied upon in the field. The district court proceeded on the policy assumption that under Rule 703,

"given the potential for open-ended receipt into evidence of testimony based upon information of questionable reliability, it is plain that some limitation on the types of information upon which an expert may rely is essential." *Zenith Radio Corp.* v. *Matsushita Elec. Indus. Co.*, 505 F. Supp. 1313, 1323 (E.D. Pa. 1980). It justified this view on the argument that, because much information relied on under Rule 703 is hearsay, Rule 703 is "essentially a shorthand translation of the hearsay rules' trustworthiness element." *Id.* at 1324. The district court therefore concluded that "the judge must be the ultimate arbiter of the reliability of materials upon which an expert witness bases his opinion," noting that "any other result would open the door to the wholesale admission of otherwise inadmissible evidence before the jury . . . [which] could not have been contemplated by the rule." *Id.* at 1326. The district court articulated a six-part test for guarding this door. *Id.* at 1330.

The Third Circuit disagreed. It found that "the trial judge misapplied Rule 703 in concluding that he, not the experts in the field, was the source of information about reasonable reliance," 723 F.2d at 280. In a thorough review of the language and history of the provision, the circuit court made amply clear that, where there is a dispute under Rule 703, the trial court must determine the issue *on the trial record before it,* and "[t]he proper inquiry is not what the *court* deems reliable, but what experts in the relevant discipline deem it to be. . . . [T]he district court must make a *factual* inquiry and finding as to *what data experts in the field find reliable*." *Id.* at 276-77 (emphasis added). It explained that the roots of Rule 703 ran too deep to allow room for policy adjustments by the courts:

> The indice of reliability under Rule 703 is the fact that experts in the field in question rely on the type of data in forming their opinions. . . . It was this view which the drafters incorporated in Rule 703.

> They did so over significant opposition. What the trial court did in effect was to reject the decision of the Judicial Conference, the Supreme Court, and Congress and adhere to an unusually restrictive view as to the basis on which an expert's opinion may be laid.

Id. at 277 (citation omitted).

Given that there were "in the record unequivocal and uncontradicted affidavits" attesting to reasonable reliance, *id.* at 276, there could be only one finding under Rule 703. The circuit court agreed with the district court that the assumptions and conclusions of such experts should be subject to rigorous examination, but it stressed that this must be done in cross-examination because "the fact-finder can be expected to determine the appropriate weight to be given to the testimony." *Id.* at 277-78.

In so reading Rule 703, the Third Circuit agreed with an equally forceful opinion by the Sixth Circuit.[9]

Since the Third Circuit's seminal opinion, the circuits have diverged sharply. The Third Circuit has held to its standard,[10] as has the Sixth.[11] It has been joined by the First Circuit,[12] the

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[9] *Mannino* v. *International Mfg. Co.*, 650 F.2d 846, 851 (6th Cir. 1981) ("The purpose of Rule 703 is to make available to the expert all of the kinds of things that an expert would normally rely upon in forming an opinion, without requiring that these be admissible in evidence. Under the Rule, the expert is free to give his opinion in his area of expertise. In short, through Rule 703, the law is catching up with the realities of professional life."); *id.* at 853 ("Great liberality is allowed the expert in determining the basis of his opinions under Rule 703").

[10] *Indian Coffee Corp.* v. *Procter & Gamble Co.*, 752 F.2d 891, 894-95 (3rd Cir. 1985), *cert. denied*, 474 U.S. 863 (1985).

[11] *AU Rustproofing Center, Inc.* v. *Gulf Oil Corp.*, 755 F.2d 1231, 1238 (6th Cir. 1985).

[12] *International Adhesive Coating Co., Inc.* v. *Bolton Emerson Intn'l*, 851 F.2d 540, 544 (1st Cir. 1988) ("As noted in Rule 703, such reasonableness is measured against the facts or data upon which experts in the particular field

Fourth,[13] the Seventh,[14] and the Eighth.[15]

Several other Circuits, however, have followed the lead of the district court in the *Japanese Antitrust* case: the Second Circuit,[16] a number of decisions in the Fifth Circuit,[17] and at least one decision in the Tenth Circuit.[18] The Ninth Circuit does not appear to have taken sides on this issue,[19] nor does the Eleventh.[20]

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normally rely."); *id.* at 545 ("When the factual underpinning of an expert's opinion is weak, it is a matter affecting the weight and credibility of the testimony — a question to be resolved by the jury.").

[13] *Clinchfield Railroad Co.* v. *Lynch*, 784 F.2d 545, 554 (4th Cir. 1986).

[14] *United States* v. *Bramlet*, 820 F.2d 851, 856 (7th Cir. 1987), *cert. denied*, 484 U.S. 861 (1987); *United States* v. *Lundy*, 809 F.2d 392, 395-96 (7th Cir. 1987).

[15] *Hurst* v. *United States*, 882 F.2d 306, 311 (8th Cir. 1989); *Cashman* v. *Allied Products Corp.*, 761 F.2d 1250, 1255 (8th Cir. 1985).

[16] *United States* v. *Daly*, 842 F.2d 1380, 1387 (2d Cir. 1988), *cert. denied*, 109 S.Ct. 66 (1988); *Shatkin* v. *McDonnell Douglas Corp.*, 727 F.2d 202, 208 (2d Cir. 1984) (noting that district court had "the discretionary right under Fed.R.Evid. 703 to determine whether the expert acted reasonably in making assumptions of fact upon which he would base his testimony").

[17] *E.g.*, *Washington* v. *Armstrong World Indus.*, 839 F.2d 1121, 1123 (5th Cir. 1988), and *Viterbo* v. *Dow Chemical Company*, 826 F.2d 420, 422 (5th Cir. 1987) (allowing independent scrutiny of reliability). The Fifth Circuit seems very much in conflict with itself on this issue. *Compare Christopherson* v. *Allied-Signal Corp.*, 902 F.2d 362, 364 (5th Cir. 1990), and *Peteet* v. *Dow Chemical Co.*, 868 F.2d 1428, 1432 (5th Cir. 1989), *cert. denied*, 110 S.Ct. 328 (1989) (both appearing to apply more liberal standard).

[18] *Head* v. *Lithonia Corp.*, 881 F.2d 941, 943-44 (10th Cir. 1989). This may be the minority view in the circuit. *Compare Wilson* v. *Merrell Dow Pharmaceuticals*, 893 F.2d 1149, 1153-55 (10th Cir. 1990) and *Marsee* v. *United States Tobacco Co.*, 866 F.2d 319, 323 (10th Cir. 1989) (both taking more liberal approach).

[19] *See, e.g.*, *Cabrales* v. *County of Los Angeles*, 864 F.2d 1454, 1460 (9th Cir. 1988), *cert. denied*, 109 S.Ct. 1931 (1989), *cert. denied*, 110 S.Ct. 20 (1989); *State Farm Fire and Casualty Co.* v. *Jenner*, 856 F.2d 1359, 1365 (9th Cir. 1988), *superseded*, 874 F.2d 604 (9th Cir. 1989).

[20] *See, e.g.*, *United States* v. *Scrima*, 819 F.2d 996, 1002 (11th Cir. 1987); *United States* v. *Ramos*, 725 F.2d 1322, 1324 (11th Cir. 1984).

The decision of the court below adds yet a third — and a particularly aberrant — interpretation of the "reasonably relied upon" standard of Rule 703. The D.C. Circuit's view cannot be squared with that of the First, Third, Fourth, Sixth, Seventh and Eighth Circuits, which hold that all that is relevant is what experts do in practice. Nor can it be squared with the view shared by the Second, Fifth and Tenth Circuits that some degree of second-guessing of the reasonableness of the information relied upon, *but based wholly on the record of the case and on the testimony of the experts as to what they deem reasonable*, is proper, for these decisions do not call for a legislative-type judgment about the general validity of the expert's ultimate opinion, as the court below did.

This three-way split over the meaning of Rule 703 should be allowed to fester no longer. The Senate Report accompanying the bill that became the Federal Rules of Evidence cited the need for "a comprehensive code of evidence intended to govern the admissibility of proof in all trials before the Federal courts because of the lack of uniformity and clarity in the present law of evidence on the Federal level." [1974] U.S. Code Cong. & Ad. News 7054. That legislative aim plainly cannot be maintained unless this Court resolves persistent circuit conflicts over rules that are integral to large numbers of trials conducted each day throughout the nation.

2. This Court should resolve the conflict between the decision below and the decisions of this Court and of other circuits over the standard for appellate review of trial court determinations of the admissibility of expert opinion evidence.

Apart from the turmoil in the circuits over the *substantive* standard to be applied by a court under Rule 703 in determining what information is "reasonably relied upon" by experts in the field, there is even greater uncertainty over the *standard for*

review by appellate courts in reviewing trial court decisions whether to admit such evidence under Rule 104(a).

It is true that the Federal Rules of Evidence, "like the other modern codifications, do not provide any standard for appellate review of the trial court's determination of disputed preliminary facts." 21 C. Wright & K. Graham, *Federal Practice and Procedure* § 5053, at 264 (1977). Here, however, the consistent decisions of this Court provide a benchmark for review. More than a century ago, this Court held:

> Whether a witness is shown to be qualified or not as an expert is a preliminary question to be determined in the first place by the court . . . . Cases arise where it is very much a matter of discretion with the court whether to receive or exclude the evidence; but the appellate court will not reverse in such a case, unless the ruling is manifestly erroneous.

Spring Co. v. *Edgar*, 99 U.S. 658 (1879). This Court reiterated in *Salem* v. *United States Lines Co.*, 370 U.S. 31, 35 (1962), that "the trial judge has broad discretion in the matter of the admission or exclusion of expert evidence, and his action is to be sustained unless manifestly erroneous."

The "manifest error" standard is aptly suited to the expert testimony context, where difficult decisions about the qualification of an expert, the value of testimony to the trier of fact, the reasonableness of the grounds relied upon, and the like, require the trial judge's intimate familiarity with the facts of the litigation. Outside the D.C. Circuit, four circuits now adhere to Salem's "manifestly erroneous" standard for review of Rule 703 rulings.[21] Six circuits employ the less deferential

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[21] *United States* v. *Daly*, 842 F.2d 1380, 1387-88 (2d Cir. 1988), *cert. denied*, 109 S.Ct. 66 (1988); *Viterbo* v. *Dow Chemical Company*, 826 F.2d

"abuse of discretion" standard.[22] One employs a "clearly erroneous" test.[23]

If this confusion had not itself merited review long ago, the decision of the court surely renders the situation intolerable. For the court below ignored hornbook law that "[t]he question whether reliance by an expert is reasonable as required by FRE 703 involves a *factual* judgment to be made by the *trial* judge pursuant to Rule 104(a) . . . ." 3 D. Louisell & C. Mueller, *Federal Evidence* § 389, at 418 (West 1988 Supp.) (citations omitted) (emphasis added). At least all other circuits exhibit *some* deference to Rule 703 trial court determinations, recognizing their quintessentially factual character. By uniquely treating the question of how experts actually conduct their affairs as a "matter of law,"[24] the court below ignored the whole point of the law in this area. As this Court has observed: "The [Advisory Committee] Note to Rule 104 specifically addresses

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420, 422 (5th Cir. 1987); *Cravens* v. *County of Wood*, 856 F.2d 753, 755-56 (6th Cir. 1988); *Brown* v. *Sierra Nevada Memorial Miners Hosp.*, 849 F.2d 1186, 1191 (9th Cir. 1988).

[22] *International Adhesive Coating Co., Inc.* v. *Bolton Emerson Intn'l*, 851 F.2d 540, 544 (1st Cir. 1988); *Soden* v. *Freightliner Corp.*, 714 F.2d 498, 502-03 (5th Cir. 1983); *United States* v. *Lundy*, 809 F.2d 392, 395-96 (7th Cir. 1987), and *Spray-Rite* v. *Monsanto Co.*, 684 F.2d 1226, 1241 (7th Cir. 1982), *reh. denied*, 466 U.S. 994 (1984), *affirmed*, 465 U.S. 752 (1984); *Hurst* v. *United States*, 882 F.2d 306, 311 (8th Cir. 1989); *Wilson* v. *Merrell Dow Pharmaceuticals*, 893 F.2d 1149, 1153-55 (10th Cir. 1990); *United States* v. *Cox*, 696 F.2d 1294, 1297 (11th Cir. 1983), *cert. denied*, 464 U.S. 827 (1983).

[23] *In Re Japanese Electronic Products Antitrust Litigation*, 723 F.2d 238, 279 (3rd Cir. 1983), *rev'd on other grounds sub nom. Matsushita Elec. Indus. Co.* v. *Zenith Radio Corp.*, 475 U.S. 574 (1986).

[24] The court of appeals is incorrect in suggesting that "[t]wo other circuits have reached similar conclusions" (A8) regarding the concept of denominating Rule 703 issues "matters of law" as a means of justifying a *de novo* review standard. In *Lynch* v. *Merrell-National Laboratories, Inc.*, 830 F.2d 1190 (1st Cir. 1987), *the trial court* concluded that the expert testimony lacked adequate foundation. *Brock* v. *Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307 (5th Cir. 1989), *cert. denied*, 110 S.Ct. 1511 (1990), is similarly irrelevant because it involved only a question of the "sufficiency of evidence" adduced at trial, *not* a determination under Rule 703, and indeed did not even mention a single federal rule of evidence.

the process by which a federal court should make the *factual* determinations requisite to a finding of admissibility: 'If the question is factual in nature, the judge will of necessity receive evidence pro and con on the issue.'" *Bourjaily* v. *United States*, 483 U.S. 171, 179 n.2 (1987) (emphasis added).

3. This Court should resolve the circuit conflict over whether a new trial is the exclusive remedy for serious evidentiary errors, or whether instead a court may order judgment n.o.v. based on a phantom record never considered by the jury.

Perhaps the most astonishing aspect of the circuit court's decision is its award of a judgment n.o.v. as the remedy for the evidentiary errors it identified. The circuit court's phantom record theory, *see supra* pp. 5-6, based on its observation that once the Ealys' expert testimony "is deemed inadmissible, it is self-evident that the evidence is insufficient to support a verdict for the plaintiffs" (A11), flouts settled law and is in conflict with a decision of this Court and flatly contradicts holdings in similar cases in two circuits.

Hornbook law is clear enough:

> The party dissatisfied with a jury verdict, as the losing party usually is, may attack it in either of two ways. He may assert that the proceeding was in some fashion so tainted with error that he should be given a new trial, or he may assert that his opponent's evidence failed to create an issue on which reasonable men could differ, and that as a matter of law the dissatisfied party should be awarded judgment notwithstanding the verdict.

C. Wright, *Federal Courts* 633 (4th ed. 1983).

This Court carefully explained the distinction between the two motions soon after the Federal Rules of Civil Procedure were adopted, in *Montgomery Ward & Co.* v. *Duncan*, 311 U.S. 243 (1940). It made clear that arguments "that the court erred in rulings on evidence and in refusing requested instructions" are proper on a motion for a new trial, but that such grounds are "not appropriate to be considered in connection with the motion for judgment" under Fed. R. Civ. P. 50(b). *Id.* at 249. And it observed: "Each motion, as the rule recognizes, has its own office. The motion for judgment cannot be granted unless, as a matter of law, the opponent of the movant failed to make a case and, therefore, a verdict in movant's favor should have been directed." *Id.* at 251.

Two circuits have followed this Court's ruling and have expressly rejected the phantom record theory advanced by the court of appeals in this case. In *Midcontinent Broadcasting Co.* v. *North Central Airlines, Inc.*, 471 F.2d 357, 358 (8th Cir. 1973), the Eighth Circuit overturned an order of judgment n.o.v. that was made "only after excluding the plaintiff's expert testimony which had been presented to the jury"; it held that "[i]n ruling on the sufficiency of evidence the trial court must take the record as presented to the jury." In *Dixon* v. *International Harvester Co.*, 754 F.2d 573, 579-80 (5th Cir. 1985), the Fifth Circuit reversed a similar j.n.o.v. grant predicated on a post-trial exclusion of expert testimony, explaining that "[t]he trial court must take the record as presented to the jury and cannot enter judgment on a record altered by the elimination of incompetent evidence." *See also Sumitomo Bank of California* v. *Product Promotions, Inc.*, 717 F.2d 215, 218 (5th Cir. 1983) (reversing similar j.n.o.v., saying "[i]t was incumbent upon the trial court to consider all of the evidence before the jury, as it was in fact presented to the jury") (panel including Wisdom, J.).

As the *Midcontinent Broadcasting* court explained, apart from the need to respect the plain meaning of Rule 50(b), these holdings are necessary to ensure that parties do not lose trials simply because they have been placed "in a relative position of unfair reliance" by lack of foreknowledge of the future finding of evidentiary error, and because after trial they are not permitted to supply "further foundation or even totally different evidence" to supplement the phantom record. 471 F.2d at 359. In this case the reliance is palpable, for nothing in the court of appeals' holding, made under *Rule 703*, could prevent petitioners from introducing opinion testimony, on retrial, as long as based on evidence in the record. For "[t]he reasonably relied upon requirement of Rule 703 applies only to facts, data or opinions not admitted in evidence."[25]

The court of appeals blithely put itself in conflict with all of the above authority. One other circuit, in *dictum*, has also questioned this authority. *Aloe Coal Company* v. *Clark Equip. Co.*, 816 F.2d 110, 115-16 (3rd Cir. 1987), *cert. denied*, 484 U.S. 853 (1987). These recent conflicts are worthy of review by this Court to ensure that the phantom record theory is either quickly exorcised from the courts, or else placed on some secure nationwide footing.

4. Review of the decision below would be a particularly appropriate exercise of this Court's supervisory power, given the troubling separation-of-powers problems posed by the circuit court's decision.

The disregard of the court below for this Court's precedents, and its casual willingness to place itself in conflict with other federal circuits on matters of federal law as to which Congress has made clear its view that national uniformity is especially important, provide ample justification for this Court's plenary

[25] Graham, *Expert Witness Testimony and the Federal Rules of Evidence: Insuring Adequate Assurance of Trustworthiness*, 1986 U. Ill. L. Rev. 43, 64.

consideration of this case. But the argument for a grant of certiorari is made even more compelling by the institutionally peculiar role that the D.C. Circuit has set for itself.

At issue here is not simply the reach and meaning of common law rules of evidence developed by the federal courts for their own administration, which were the norm before 1975. On the contrary, in light of "the jealousy with which Congress viewed Supreme Court rulemaking" in the area of evidence,[26] a political battle of some moment was waged in conjunction with the promulgation by Congress of Federal Rules of Evidence expressly to displace what would otherwise have been the more freewheeling development by the Federal Judiciary of a federal law of evidence. This Court has long acknowledged that "Congress has undoubted power to regulate the practice and procedure of federal courts," *Sibbach* v. *Wilson & Co.*, 312 U.S. 1, 9 (1941) (citations omitted). And this Court has also made clear that the Federal Rules of Evidence should be understood and interpreted for what they are — namely, Acts of Congress. *Beech Aircraft* v. *Rainey*, 109 S. Ct. 439, 446 (1988) ("Because the Federal Rules of Evidence are a legislative enactment, we turn to the 'traditional tools of statutory construction' . . . in order to construe their provisions.").

Yet there is not so much as a hint in the opinion of the court below that it felt constrained in escalating *Richardson* into a mini-statute for the D.C. Circuit, or that it approached the Federal Rules of Evidence at issue in the way that this Court has repeatedly held a federal statute enacted by Congress must be approached. Neither the plain language of those Rules nor their history and purpose gave the court below the slightest pause. It made no effort to justify its departure from the approach of other circuits in terms of its understanding of the text of Rule 703 or Rule 104(a), or in terms of its view of the purposes of those rules. Rather, it acted just as though it had

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[26] 22 C. Wright & K. Graham, *Federal Practice and Procedure* § 5198, at 219 (1977).

power fully parallel to that of the Congress of the United States to create an evidentiary regime for the D.C. Circuit, which would effectively displace the statute duly enacted for the entire nation by Congress.

Congress appears to have barred exactly this brand of judicial rulemaking, for Federal Rule of Evidence 402 provides that only the Constitution, the Federal Rules of Evidence, other statutes, or Rules promulgated by *this* Court can bar admission of evidence.[27] At the very least, it would raise a serious issue of the separation of powers for an Article III court to promulgate a code of evidence for a given circuit in the face of Congress's declaration. But no constitutional holding is needed here. This Court need only exercise its supervisory power to bring the D.C. Circuit into line with the other circuits, by ruling that the aberrant approach of the court of appeals in this instance is inconsistent with the applicable Federal Rules of Evidence.

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[27] *See also* 22 C. Wright & K. Graham, *Federal Practice and Procedure* § 5199, at 222 (1977) ("the record rather strongly suggests that Congress assumed that, except where the Evidence Rules otherwise provide, there would be no decisional law of evidence") (citations omitted).

CONCLUSION

For the reasons stated above, a writ of certiorari should be granted.

Respectfully submitted,

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August 1, 1990

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APPENDIX A

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued February 8, 1990 Decided March 9, 1990

Nos. 87-7214 & 87-7219

SEKOU EALY, ET AL.,
APPELLEES

v.

RICHARDSON-MERRELL, INC.,
APPELLANT

Appeal from the United States District Court
for the District of Columbia

Michael Nussbaum, with whom *James P. Davenport, Lori E. Fox*, and *Mark L. Austrian* were on the brief for appellant in 87-7214 and appellee in 87-7219, *Frederick D. Baxter* also entered an appearance for Richardson-Merrell, Inc.

Barry J. Nace, with whom *Irving R. M. Panzer* was on the brief, for appellees in 89-7219 and cross-appellants in 87-7214. *John J. Sellinger* also entered an appearance for Sekou Ealy, et al.

Before: MIKVA, EDWARDS and SILBERMAN, *Circuit Judges*.

Opinion for the Court filed by Circuit Judge MIKVA.

MIKVA, *Circuit Judge*: This appeal arises from a products liability action seeking recovery for a child's birth defects allegedly caused by the mother's use of Bendectin during her pregnancy. For over twenty-five years (1957-1983), Bendectin was a popular medication for morning sickness experienced during early pregnancy. In 1983, the manufacturer of Bendectin, Richardson-Merrell, Inc. ("Merrell"), voluntarily took the drug off the market although the Food and Drug Administration never rescinded approval of the drug. Bendectin has been studied extensively to determine whether it is a human teratogen, i.e. capable of causing birth defects in humans. To date, no published human population or epidemiological study has concluded that there is a statistically significant association between Bendectin and limb reduction defects of the type at issue in this case.

Merrell, the defendant-appellant in this action, appeals a jury's award of $20 million in compensatory damages for plaintiffs-appellees, the Ealys, and appeals the trial court's order denying its motions for judgment n.o.v. and denying its motions for a new trial. The Ealys cross-appeal the trial court's order granting a remittur of the jury's $75 million punitive damage award. Merrell argues that this court's decision in *Richardson* v. *Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C.Cir.), *cert. denied*, 110 S.Ct. 218 (1989) ("Richardson") requires reversal of the compensatory award. In addition, Merrell contends that the compensatory award is excessive and violates due process; and that numerous procedural errors regarding expert testimony and other evidence warrant a new trial. The Ealys counter each of these assertions, arguing, *inter alia*, that the *Erie* doctrine requires that this court follow the D.C. Court of Appeals decision in *Oxendine* v. *Richardson-Merrell, Inc.*, 506 A.2d 1100 (D.C.1986) ("*Oxendine I*").

We find that this case is squarely within the binding rule articulated in *Richardson*: an expert opinion that Bendectin is a human teratogen which caused the plaintiff's birth defects is without scientific foundation under Federal Rule of Evidence 703 in the face of "a wealth of published epidemiological data" to the contrary. 857 F.2d at 832. Accordingly such expert opinion is inadmissible. Because we discern no material difference between the evidence presented in *Richardson* and that presented in this case, we reverse the trial court's denial of the motion for judgment n.o.v. Contrary to the Ealys' assertions, neither this court nor the *Richardson* court deviated from the local tort law expressed in *Oxendine I*. Our decision in *Richardson* turned on the admissibility of expert testimony — a procedural matter which does not implicate the principles underlying *Erie Railroad Co.* v. *Tompkins*, 304 U.S. 64 (1938). It is also significant to a point of distinction that fewer scientific studies were introduced by the parties in *Oxendine I* than in either this case or the *Richardson* case.

Because we reverse on the issue of liability, we need not reach any of the other issues raised on appeal or cross-appeal.

I. BACKGROUND

Sekou Ealy was born in 1979 with congenital birth defects of his hands and arms. He has three fingers on one hand and four on the other and no thumbs. His arms are underdeveloped and locked at the elbows. Although he is otherwise a normal child, he has undergone weekly psychiatric therapy to address his mental fixation that his parents cut off his fingers to punish him for being naughty. It is undisputed that Sekou's mother took Bendectin during her pregnancy for morning sickness and that extensive evaluation has failed to disclose a clear cause for his malformations.

At trial, the plaintiffs argued that inferences drawn from analysis of Bendectin's chemical composition, *in vitro* studies of the effects of Bendectin components on animal cells in test tube cultures, *in vivo* data from studies conducted on animals given Bendectin, and unpublished reinterpretations of the epidemiological literature are sufficient foundation to support an opinion that Bendectin is a human teratogen. This was precisely the theory of proof used by the plaintiffs in *Richardson*. In developing their case, the Ealys introduced the testimony of eight expert witnesses, only one of whom did not testify in *Richardson*. This single witness, Dr. William McBride, was also the only expert witness whose testimony, introduced by deposition, was based on published studies which he himself had conducted. Based on his study of the effects of doxylamine succinate, an element of Bendectin, on rabbits and marmosets, Dr. McBride opined that Bendectin is a human teratogen.

After hearing the expert testimony, the jury reached a verdict for the plaintiff, awarding $20 million in compensatory damages and $75 million in punitive damages. The trial court rejected the defendant's argument, on motion for judgment n.o.v., that the verdict was without scientific foundation, concluding instead that there was "substantial conflicting evidence" about which reasonable people could differ. The court also noted that two other juries in similar Bendectin cases tried in the district court had reached verdicts for the plaintiffs. One of those verdicts was later set aside in *Richardson* and the other is pending decision on a post-trial motion to set aside the verdict on the authority of *Richardson*. The trial court upheld the compensatory damages award, finding that the $20 million figure did not "shock the conscience" of the court. The court set aside the punitive damages award because there was no evidence of willful disregard or outrageous conduct by the manufacturer.

II. DISCUSSION

A. *Standard of Review*

In *Richardson*, this court affirmed a judgment n.o.v. in favor of Merrell, holding that an expert opinion that Bendectin caused a child's limb reduction defects was inadmissible based on the record developed in that case. 857 F.2d at 832. Appellant Merrell now argues that the *Richardson* decision provides a binding legal precedent that requires reversal of the trial court's denial of its motion for judgment n.o.v. in the case *sub judice*. The standard of review of the trial court's decision on motions for judgment n.o.v. is *de novo*. As with motions for directed verdicts, the reviewing court asks the same question asked by the trial court: whether, viewing the evidence in the light most favorable to the plaintiff, and giving him every reasonable inference, the evidence is so one-sided that no reasonable juror could find on the admissible evidence that Bendectin caused the plaintiff's birth defects. *Richardson*, 857 F.2d at 827-28; McNeal v. *Hi-Lo Powered Scaffolding, Inc.*, 836 F.2d 637, 640-41 (D.C.Cir.1988). Any conflicts in evidence must be resolved in favor of the plaintiff who was the prevailing party below. *McNeal*, 836 F.2d at 641.

B. *The* Richardson *Decision*

The *Richardson* court concluded that there was not sufficient evidence in the record on which a jury could base a verdict for the plaintiff because all of the plaintiff's expert testimony — the only relevant evidence on the causation issue — was inadmissible. Relying on Federal Rule of Evidence 703, the court ruled, in essence, that the issue of scientific causation should not have been left to the jury because Dr. Alan Done's expert opinion that Bendectin caused the plaintiff's birth defects

lacked an adequate scientific foundation. Dr. Done served as the lead expert for the plaintiffs in both *Richardson* and this case. The *Richardson* court's treatment of Dr. Done's testimony subsumed that of the other experts presented on the Richardson's behalf. 857 F.2d at 829 n.38.

Rule 703 governs the "Bases of Opinion Testimony by Experts," and requires that the grounds relied upon by an expert be of "a type reasonably relied upon by experts in the particular field of forming opinions or inferences upon the subject." Fed.R.Evid. 703. The *Richardson* court noted that Dr. Done had predicated his opinion on four types of data. After canvassing the probative value of each type of data, the court concluded:

> These three types of studies then — chemical, *in vitro* and *in vivo* — cannot furnish a sufficient foundation for a conclusion that Bendectin caused the birth defects at issue in this case. Studies of this kind, singly or in combination, are not capable of proving causation in human beings *in the face of the overwhelming body of contradictory epidemiological evidence*. Perhaps mindful of this, the last type of evidence considered by Dr. Done consisted of the epidemiological studies. *When such studies are available and relevant, and particularly when they are numerous and span a significant period of time,* they assume a very important role in determinations of questions and causation.

857 F.2d at 830 (emphasis added). Every epidemiological study introduced in *Richardson* had concluded that there was *not* a statistically significant relationship between Bendectin and birth defects. The court proceeded to note Dr. Done's concession that he would not "give an opinion as to causation

without a statistically significant relationship." *Id.* Dr. Done overcame this hurdle

> [o]nly by recalculating the [published epidemiological] data . . . to obtain what he deems a statistically significant result. Moreover, the studies rejected by Dr. Done had been published in peer-reviewed scientific journals, while Dr. Done has neither published his recalculations nor offered them for peer review.

Id. at 831.

The *Richardson* court distinguished its case from our decision in *Ferebee* v. *Chevron Chemical Co.*, 736 F.2d 1529 (D.C.Cir.), *cert. denied*, 469 U.S. 1062 (1984), which addressed the question whether paraquat exposure caused pulmonary fibrosis. *Ferebee*, the *Richardson* court concluded, was an example of " 'a classic battle of the experts, a battle in which the jury must decide the victor.' " *Richardson*, 857 F.2d at 832 (quoting *Ferebee*, 736 F.2d at 1535). In *Ferebee* the defendant attempted to discredit the opinions of the plaintiff's experts on the ground that their views were sufficiently novel to be inadmissible. The *Ferebee* court stated:

> [A] cause-effect relationship need not be clearly established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists. As long as the basic methodology employed to reach such a conclusion is sound, . . . products liability law does not preclude recovery until a "statistically significant" number of people have been injured or until science has had the time

> and resources to complete sophisticated laboratory studies of the chemical.

736 F.2d at 1535-36. The *Richardson* court found *Ferebee* inapposite because it applied to cases where the causation theory is novel and " 'stand[s] at the frontier of current medical and epidemiological inquiry.' " In *Richardson*, however, the case was a great distance from the frontier of "epidemiological inquiry," because studies had been conducted and published for twenty-odd years. 857 F.2d at 832.

The *Richardson* court concluded, as a matter of law, that the "wealth of published epidemiological data . . . none of which has concluded that the drug is teratogenic . . . must be given their just due." 857 F.2d at 832. Therefore, under Rule 703, an opinion refuting this scientific consensus is inadmissible for lack of an adequate foundation, in the absence of other substantial probative evidence on which to base this opinion. It is this uncontroversial rule of evidence that is the *ratio decidendi* of *Richardson* and this case.

Two other circuits have reached similar conclusions. *See Lynch* v. *Merrell-National Laboratories, Inc.*, 830 F.2d 1190 (1st Cir.1987); *Brock* v. *Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307 (5th Cir.), *modified*, 884 F.2d 166 (5th Cir.), *reh'g denied*, 884 F.2d 167 (5th Cir.1989) (*en banc*). The First Circuit opined that "[a] new [epidemiological] study coming to a different conclusion and challenging the consensus would be admissible evidence. Without such a study there is nothing on which expert opinion on Bendectin as a cause may be based." *Lynch*, 830 F.2d at 1194; *cf. In Re "Agent Orange" Prod. Liab. Litig.*, 611 F.Supp. 1223, 1242 (E.D.N.Y.1985) ("When the expert's . . . testimony lie[s] at the periphery of what the scientific community considers acceptable, special care should be exercised in evaluating the reliability and probative worth of the proffered testimony under Rules 703 and

403."). Unlike the circumstances of *Ferebee*, the body of *published* epidemiological opinions on the subject at hand is extensive, indeed massive, and all such opinions point to the same conclusion. As *Richardson* teaches, this is our measuring rod for scientific adequacy.

Because *Richardson* provides a binding legal precedent governing the admissibility of expert opinion on the ability of Bendectin to cause human birth defects, the Ealys can only avoid that decision by showing that the record here is materially different from that in *Richardson*. We find no such difference.

C. *Evidentiary Differences*

Merrell argues that there are no material differences between this case and *Richardson* because the Ealys have not pointed to any new epidemiological studies on Bendectin not introduced in *Richardson*. The Ealys do not refute that the epidemiological studies are identical in both cases. Here, as in *Richardson*, the plaintiff's epidemiology expert, Dr. Shanna Swan, tried to refute the validity of the published epidemiological data through her own unpublished reanalysis. The chemical structure, *in vivo*, and *in vitro* studies relied upon by the Ealys are also virtually the same as those referenced in *Richardson* with one exception: Dr. McBride testified by deposition as an expert for the Ealys but not for the plaintiffs in *Richardson*. He testified about his *in vivo* studies of the effects of doxylamine succinate on rabbits and marmosets. This data, however, along with all the other *in vivo, in vitro,* and chemical structure data, has dubious significance in the face of the epidemiological data.

The Ealys make no effort to point out differences in the scientific studies introduced in the two cases. Instead, they attempt to distinguish this case from that of *Richardson* by focusing on specific statements made by various experts on

both sides that were not made in *Richardson*. None of these differences are material. According to *Richardson*, none of the evidence relied upon by the Ealys' experts, either singly or in combination, provides an adequate scientific foundation to render the plaintiff experts' opinions on human causation admissible. The Ealys offer nothing to alter this conclusion.

D. *The* Erie *Doctrine*

Equally unavailing is the Ealys' contention that the *Erie* doctrine requires this court to follow the D.C. Court of Appeals decision in *Oxendine I*. That Bendectin case, which was litigated in the D.C. Superior Court, resulted in a verdict for the plaintiff. The trial judge then granted a judgment n.o.v. for Merrell, but the D.C. Court of Appeals reversed the trial judge and reinstated the jury verdict. *Oxendine I*, 506 A.2d 1100 (D.C.1986). The jury verdict was affirmed on other grounds in *Oxendine* v. *Merrell-Dow Pharmaceuticals, Inc.*, 563 A.2d 330 (D.C.1989) ("*Oxendine II*"). The same four types of data relied upon by the Ealys were involved in the *Oxendine* case. The court in *Oxendine I* conceded that each individual class of data showed "little or nothing when viewed separately from one another," but reasoned that their sum formed a "mosaic" greater than its parts, providing "a foundation for Dr. Done's opinion that Bendectin caused appellant's birth defects." *Oxendine I*, 506 A.2d at 1100.

The *Richardson* court specifically rejected the argument that it was required to follow *Oxendine I* because it was sitting in a diversity action on a state tort claim:

> [T]he Richardsons' *Erie* challenge must be rejected. We note that the Richardsons' argument ignores the differences in the evidence presented in the two cases. Moreover, the *Erie* doctrine applies to state

> *substantive*, not *procedural*, law to be followed by federal courts exercising diversity jurisdiction. . . . Because the admissibility of testimony, which is governed by the Federal Rules of Evidence, is the crux of our decision in this case . . . the Richardsons' argument must be rejected.

Richardson, 857 F.2d at 825 n.9 (citations omitted). As our discussion thus far has shown, this case, like *Richardson*, turns on the admissibility of the expert testimony. Unfortunately for the Ealys, the only evidence they have on the issue of scientific causation is the testimony of their experts. Once that testimony is deemed inadmissible, it is self-evident that the evidence is insufficient to support a verdict for the plaintiffs. Contrary to the Ealys' assertions, however, this court is enforcing a procedural rule governing admissibility; it is not supplanting substantive state rules on the sufficiency of evidence.

In any event, the *Oxendine I* court's reasoning would not be directly exportable to the Ealys' cause because, as with *Richardson*, there are material differences between the evidence in each case. *Oxendine I* was tried in 1983, *Richardson* in 1986, and the Ealys' case in 1987. In the intervening years, two large epidemiological studies were published which found no association between Bendectin and birth defects.

III. CONCLUSION

It may well be that future scientific research will generate new epidemiological or other types of data providing an adequate basis for an expert's opinion that Bendectin is a human teratogen that caused a plaintiff's birth defects. Until that day, the existing body of published epidemiological studies, all finding no significant statistical association between ingestion of Bendectin and birth defects, must be recognized

as the measuring stick for the admissibility of expert testimony on this issue. On this narrow, procedural issue, this case is the same as *Richardson*. We reverse the trial judge's denial of judgment n.o.v. because the expert opinion that Bendectin caused Sekou Ealy's limb defects was without scientific foundation. We remand to the district court to enter a judgment n.o.v. for Merrell. This conclusion disposes of all other issues raised on appeal and cross-appeal.

So ordered.

APPENDIX B

United States District Court

FOR THE DISTRICT OF COLUMBIA

SEKOU EALY, et al.	)	
Plaintiffs	)	
v.	)	Civil Action
RICHARDSON-MERRELL, INC.	)	No. 83-3504
Defendant	)	

FILED Oct. 1, 1987
James F. Davey, Clerk

MEMORANDUM

This matter is before the Court on defendant Merrell Dow Pharmaceuticals, Inc.'s [1] ("Merrell Dow") motion for judgment notwithstanding the verdict, or, in the alternative, a new trial or remittitur ("Defendant's Motion"); plaintiffs' opposition thereto; defendant's reply, and the entire record. For the reasons given below, the Court grants defendant's motion in part and denies defendant's motion in part.

I. BACKGROUND

The bifurcated trial in this matter was held on June 15 through July 14, 1987. On July 10, 1987, the jury returned a verdict in favor of the minor plaintiff Sekou Ealy on the issue of liability after answering affirmatively a set of special interrogatories. On July 14, 1987, the jury next returned a judgment of $20 million in compensatory damages and $75 million in punitive damages. Defendant Merrell Dow immediately moved for a directed verdict as to both the compensatory and punitive

[1] Defendant Merrell Dow Pharmaceuticals, Inc. ("Merrell Dow") was sued originally under its former name, Richardson-Merrell, Inc.

damages. July 14, 1987 Transcript at 5. The Court denied defendant's motion as to the compensatory damages but took the question of punitive damages under consideration. *Id.*

Defendant has now filed a motion for judgment notwithstanding the verdict, or, in the alternative, a new trial or remittitur as to the issues of liability and damages. In its motion defendant states that the finding of liability in this case was not justified by the state of medical knowledge about Bendectin as it existed in 1978. Defendant's Memorandum of Law in Support of Motion for Judgment Notwithstanding the Verdict, for a New Trial and a Reduction in the Amount of the Verdict ("Defendant's Memorandum") at 2. Moreover, defendant claims that the jury's verdict is based on extraordinary passion, sympathy, and prejudice for the child's birth defects. The jury, defendant contends, completely "disregard[ed] an entire body of medical and scientific literature [concerning Bendectin] and the conclusions of governmental agencies whose responsibility it was to regulate pharmaceutical manufacturers and review the safety of medications [like Bendectin which were] prescribed for the general public." *Id.*

Plaintiffs oppose defendant's motion and aver that they presented sufficient evidence to support the jury's verdict on both the issues of liability and damages. Plaintiffs state that the seriousness of the injuries sustained by the minor plaintiff, Sekou Ealy, due to his mother's ingestion of Bendectin during pregnancy — nonbending elbows, the abnormal length of his forearms, the absence of thumbs, and the missing fingers— more than justify the compensatory damages awarded by the jury. Plaintiffs' Opposition to Defendant's Various Post-Trial Motions ("Plaintiffs' Opposition") at 24.

II. DISCUSSION

A. *Motion for Judgment Notwithstanding the Verdict ("Motion for J.N.O.V.")*

"The standard for awarding a judgment n.o.v. is the same as that applied when ruling on a motion for a directed verdict." *Coburn* v. *Pan American World Airways, Inc.*, 711 F.2d 339, 342 (D.C. Cir.), *cert. denied*, 464 U.S. 994 (1983) (citation omitted). Since a motion for j.n.o.v. intrudes upon the jury's domain, the question asked by a court in considering such a motion is a narrow one. A motion for j.n.o.v. should be denied unless "'there can be but one reasonable conclusion' drawn from the evidence viewed in the light most favorable to the plaintiffs . . ., giving them the advantage of every fair and reasonable inference that the evidence may justify.'" *Metrocare* v. *Washington Metropolitan Area Transit Authority*, 679 F.2d 922, 924-25 (D.C. Cir. 1982) (quoting *Foster* v. *Maryland State Savings and Loan Ass'n*, 590 F.2d 928, 930 (D.C. Cir. 1978), *cert. denied*, 439 U.S. 1071 (1979)). *See also Vander Zee* v. *Karabatsos*, 589 F.2d 723, 726 (D.C. Cir. 1978), *cert. denied*, 441 U.S. 962 (1979). "If fair-minded people may differ as to the conclusion, or if there is substantial conflicting evidence, the judgment n.o.v. motion must be denied." *Carter* v. *Duncan-Huggins, Ltd.*, 727 F.2d 1225, 1227 (D.C. Cir. 1984). A trial court must consider all the evidence offered but it may not assess the credibility or weigh the evidence. *Metrocare*, 679 F.2d at 925 (citing *Boutros* v. *Riggs National Bank, D.C.*, 655 F.2d 1257, 1258 (D.C. Cir. 1981)). These functions are reserved strictly for the jury. *Carter*, 727 F.2d at 1228.

After a careful review of the entire record, the Court concludes that defendant's motion for j.n.o.v. must be denied. Viewing all the evidence and the reasonable inferences therefrom in the light most favorable to the plaintiffs, the Court finds

that fair-minded people could differ as to the conclusion drawn by the jury on the issue of liability in this case. Both plaintiff and defendant presented substantial conflicting evidence on the issue of causation. Based on this evidence, the jurors in this case decided to make a determination in plaintiffs' favor as have two other juries in this court in similar Bendectin cases. *See Raynor* v. *Richardson-Merrell,* Civil Action No. 83-3506 ($300,000 compensatory damages) and *Richardson* v. *Richardson-Merrell,* Civil Action No. 83-3505 ($1.16 million in compensatory damages).[2] Accordingly, the Court denies defendant's motion for j.n.o.v.

B. *Motion for New Trial or Remittitur*

Defendant has moved, in the alternative, for a new trial or remittitur of the compensatory and punitive damages awards. "When [a] court, after viewing the evidence concerning damages in a light most favorable to the prevailing party, determines that the damages award is excessive, it has two alternatives. It may grant [the] defendant's motion for a new trial or deny the motion conditional upon the prevailing party accepting a remittitur." *Fenner* v. *Dependable Trucking Co., Inc.,* 716 F.2d 598, 603 (9th Cir. 1983) (footnote omitted). The Court must give the prevailing party "the option of either submitting to a new trial or of accepting a reduced amount of damages which the court considers justified." *Id.*

"The rationalization for, and use of, the remittitur is well established as a device employed when the trial judge finds that a decision of the jury is clearly unsupported and/or excessive." *Spence* v. *Bd. of Educ. of Christina School Dist.,* 806

[2] Both of these cases have been appealed to the United States Court of Appeals for the District of Columbia Circuit. In particular, the Court notes that Judge Thomas P. Jackson granted defendant Merrell Dow's motions for judgment notwithstanding the verdict and for a new trial, in the alternative in *Richardson* v. *Richardson Merrell, Inc.,* 649 F. Supp. 799 (D.D.C. 1986).

F.2d 1198, 1201 (3d Cir. 1986) (citations omitted). A "district judge is in the best position to evaluate the evidence presented and determine whether or not the jury has come to a rationally based conclusion." *Id.* A judge must weigh all the evidence on damages and exercise its considered judgment as to a rational verdict in a judicial manner. *Edynak* v. *Atlantic Shipping Inc. Cie. Chambon*, 562 F.2d 215, 226 (3d Cir. 1977), *cert. denied*, 434 U.S. 1034 (1978); *see generally Taylor* v. *Washington Terminal Co.*, 409 F.2d 145, 148, *cert. denied*, 396 U.S. 835 (1969). A court will not reduce a jury award unless its sense of justice is shocked by the amount.

1. *Compensatory Damages*

Defendant contends that the compensatory damages award of $20 million is based on "sympathy and emotion and not on any quantifiable evidence." Defendant's Memorandum at 38. Defendant claims that plaintiffs presented no evidence to the jury which would assist it in its damages determination. Defendant points to plaintiffs' failure to present any expert testimony regarding (a) the percentage of loss of function of the minor plaintiff's limbs; (b) plaintiff's potential loss of future earnings due to his injuries, or (c) his potential future or past medical expenses, in support of its contention. *Id.* Plaintiffs, on the other hand, assert that the seriousness and permanency of the injuries suffered by the minor plaintiff precludes the suggestion that the compensatory damages award was outside the realm of reasonableness and, therefore, excessive. They ask the Court to consider the nature of the minor plaintiff's injuries, both physical and psychological.

"[T]he proper measure of damages in a tort action is compensation. 'The purpose of compensatory damages . . . is to place the injured person as nearly as possible in the condition he would have occupied if the wrong had not occurred.'" *Pizani* v. *M/V Cotton Blossom*, 669 F.2d 1084, 1088 (5th Cir. 1982) (quoting *Freeport Sulphur Co.* v. *S/S Hermosa*, 526 F.2d

300, 304 (5th Cir. 1976)). *See also* RESTATEMENT (SECOND) OF TORTS § 903 comment a (1977).

After consideration of the compensatory damages award, the Court finds that the $20 million does not shock its conscience and is, therefore, not excessive. If tried to the Court, the Court would probably have found a lesser sum, but the plaintiffs presented their case to a jury. During the trial in the matter, the jury heard a substantial amount of testimony about the minor plaintiff's injuries. The testimony revealed that the 8-year-old plaintiff was born with three digits on the right hand, four digits on the left hand, and he is missing the thumb on both hands. The child already has had two operations on his fingers and hands. *See* Transcript ("Tr.") at 915, 4177-79. One operation was performed to attempt rotation of one of his fingers on the left hand so that he could have opposition movement in the hand. After the second operation, the minor plaintiff developed a fixation that he had been naughty and his parents had punished him by having his fingers cut off. Tr. at 4178. The plaintiff is currently undergoing weekly therapy with Dr. Frank Putnam, a child psychiatrist at Children's Hospital in Washington, D.C., to help him deal with this fixation and his "everyday problems." Tr. at 4174. Both of plaintiff 's elbows are locked and he is unable to rotate his left wrist. The plaintiff is expected to experience problems with his wrist in the future, thereby necessitating an operation on it when he reaches adulthood. Tr. at 922, 924, and 926. His mother also testified about the prospect of future surgeries to correct the locked elbows. Tr. at 4179. She stated that if the elbows were operated on now, plaintiff would require at least four operations at various stages of growth.

The jury also heard testimony by the minor plaintiff, his mother, and sister about the limitations that plaintiff must face on a daily basis due to his limb injuries. He has problems with activities that require extending his arms. For example, he can-

not brush the back of his hair, button the top button of his shirt, or completely zip up a zipper, and his mother or family member must assist him with these simple acts. Tr. at 4175-76. Plaintiffs also presented evidence regarding the minor plaintiff's life expectancy of 63.2 years, Tr. at 4237, and that his impaired condition will continue through life.

The jury considered properly the aforementioned testimony in its deliberations. The Court instructed them to consider the minor plaintiff's "physical pain and suffering, past and future, his mental pain and suffering, past and future, his age, the nature and extent of his injuries, whether the injuries are permanent, the physical impairment and the disfigurement," Tr. at 4236, in fixing the amount of compensatory damages.

It is true, as pointed out by defendant, that plaintiffs did not present any expert testimony during the damages phase of this trial as is "customary" in this type of case. This fact alone, however, does not lead the Court to conclude that the jury's compensatory damages award was based solely on "sympathy and emotion and not on any quantifiable evidence" as asserted by defendant. The use of expert testimony is a matter of individual choice and litigation strategy and by no means a prerequisite to a presentation of evidence to a jury on the issue of damages. Plaintiffs, like defendant, chose not to present any expert testimony to assist the jury in its deliberations and the Court cannot penalize them for that decision. Accordingly, the Court finds that the testimony of plaintiffs' witnesses provided a sufficient basis for the jury to base its award and the Court will not disturb the $20 million compensatory damages award.

2. *Punitive Damages*

Defendant next contends that "[t]he jury's $75 million punitive damage award against [it] based on the claims of these plaintiffs is so shockingly excessive that the jury's punitive damage verdict is manifestly the product of caprice, passion

and prejudice, especially in light of the absence of conduct justifying punitive damages." Defendant's Memorandum at 34. Defendant asserts that the $75 million punitive damages award "is so inordinate as to obviously exceed the maximum limit of a reasonable range within which the jury may properly operate, [and] remittitur or a new trial is required." *Id.* (citations omitted). Moreover, defendant claims that the Court instructed the jury improperly on the issue of punitive damages. Defendant avers that "[t]here was a total lack of evidence that as of 1978[,] management at Merrell Dow acted intentionally, willfully, or recklessly" in its manufacture, production, and distribution of Bendectin as an antinauseant drug. *Id.*

Plaintiffs contend that "the evidence presented to the jury in this case reveals a longstanding corporate policy of reckless indifference and disregard of the rights of the [minor plaintiff] and others similarly situated which justified the imposition of punitive damages in this case." Plaintiffs' Memorandum at 30. Plaintiffs assert that the $75 million punitive award should be allowed to stand. After careful consideration of both parties' arguments, the Court finds that the evidence presented in this case cannot support an award of punitive damages.

Punitive damages are not favored by law. They are awarded to punish and deter outrageous conduct, and the question is whether a defendant's conduct 'contains elements of intentional wrongdoing or conscious disregard' for plaintiff's rights." *Knippen* v. *Ford Motor Co.*, 546 F.2d 993, 1002 (D.C. Cir. 1976) (citations omitted). "The focus [of punitive damages] is on the character of the tort-feasor's conduct — whether it is of the sort that calls for deterrence and punishment over and above that provided by compensatory awards." *Smith* v. *Wade*, 461 U.S. 30, 54 (1983). Injury alone will not justify an award of punitive damages. *American Medical Nursing Centers-Greenbrook* v. *Heckler*, 592 F. Supp. 1311, 1313 (D.D.C. 1984). "Actual malice is not required but defendant must act

with such conscious and deliberate disregard of the consequences of his actions to others that his conduct is wanton." *Knippen*, 546 F.2d at 1002 (citing W. PROSSER, LAW OF TORTS, § 2, at 9-10 (1971)). Conduct amounting to mere inadvertence or even gross negligence is an insufficient basis upon which to support a punitive damages award. *Rieser* v. *District of Columbia*, 563 F.2d 462, 481 n.100 (D.C. Cir. 1977) (citations omitted). "The elements justifying punitive damages must be 'clearly established'." *Raynor* v. *Richardson-Merrell, Inc.*, 643 F. Supp. 238, 245 (D.D.C. 1986) (citing *Darrin* v. *Capital Transit Co.*, 90 A.2d 823, 825 (D.C. Mun. App. 1952)). In product liability actions, "this burden has been equated with the clear and convincing standard of proof." *Id.* (citations omitted).

Viewing the entire record in this case, the Court concludes that plaintiffs failed to carry their burden of proof as to the issue of punitive damages. Plaintiffs presented no clear and convincing evidence that defendant Merrell Dow acted with conscious and deliberate disregard of plaintiffs' rights when it produced, manufactured, and distributed Bendectin prior to 1978, the year minor plaintiff's mother ingested Bendectin. In dismissing plaintiffs' fraud claim, the Court found previously that no showing of fraud had been made and at most, plaintiffs had shown gross negligence on the part of defendant. Tr. at 3900-01. As stated earlier, gross negligence is insufficient to support a claim for punitive damages. *Supra* at 12 [A20-A21]. Accordingly, the Court grants a remittitur on the entire punitive damages award of $75 million.

"Except when 'it is apparent as a matter of law that certain identifiable sums included in the verdict should not have been there,' a trial judge should not unconditionally reduce the amount of damages awarded by verdict, for to do so impermissibly encroaches upon the litigants' constitutional right to a jury." *Carter* v. *District of Columbia*, 795 F.2d 116, 134 (D.C.

Cir. 1986) (quoting 11 C. WRIGHT & A. MILLER, FEDERAL PRACTICE AND PROCEDURE, § 2815, at 99 (1973)). *See also* 6A J. MOORE, MOORE'S FEDERAL PRACTICE ¶59.08[7], at 208-09 (2d ed. 1986). However, if a district court, "employing a special verdict, erroneously allows the jury to render an award of punitive damages, for example, that segregated, precisely stated award would be readily identifiable as relating to a wholly discrete issue of law, and the special verdict could be rectified by the court without further jury proceedings." *Carter*, 795 F.2d at 134 (citing *Newport* v. *Fact Concerts, Inc.*, 453 U.S. 247, 256 n.12 (1981) and *Scottish Union & National Ins. Co.* v. *Bejcy*, 201 F.2d 163, 166 (6th Cir. 1953)).

It is the Court's "prerogative to enter a remittitur by fiat" under these circumstances, and it need not "pose to plaintiffs the choice between consent to the reduction and a trial." *Carter*, 795 F.2d at 135. By so ruling, the parties avoid the expense of a new trial, the seventh amendment right to a jury is protected due to the minimal interference with the jury function, and the final verdict is identical to that which would have been reached in a completely proper trial.

III. CONCLUSION

For the reasons given above, the Court denies defendant's motion for j.n.o.v.; denies defendant's motion for remittitur as to the $20 million compensatory damages award; grants defendant's motion for remittitur as to the $75 million punitive damages award, and denies defendant's motion for a new trial. An appropriate order is attached.

/s/ JUNE L. GREEN
U.S. DISTRICT JUDGE

Dated: October 1, 1987

United States District Court

FOR THE DISTRICT OF COLUMBIA

SEKOU EALY, et al.	)	
Plaintiffs	)	
v.	)	Civil Action
RICHARDSON-MERRELL, INC.	)	No. 83-3504
Defendant	)	

FILED Oct. 1, 1987
James F. Davey, Clerk

ORDER

Upon consideration of defendant Merrell Dow Pharmaceuticals, Inc.'s motion for judgment notwithstanding the verdict, or, in the alternative, a new trial or remittitur ("Defendant's Motion"); plaintiffs' opposition thereto; defendant's reply; for the reasons set forth in the accompanying memorandum, and the entire record herein, it is by the Court this 1st day of October 1987,

ORDERED that defendant's motion for judgment notwithstanding the verdict is denied; it is further

ORDERED that defendant's motion for remittitur as to the $20 million compensatory damages award is denied; it is further

ORDERED that defendant's motion for remittitur as to the $75 million punitive damages award is granted; and it is further

ORDERED that defendant's motion for a new trial is denied.

/s/ JUNE L. GREEN
U.S. DISTRICT JUDGE

APPENDIX C

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 87-7214 **September Term, 1989**
CA 83-3504

Sekou Ealy, Infant, by Robert and
Sandra Ealy, guardians, et al.

v.

Filed May 03 1990

Richardson-Merrell, Inc.,
a Delaware Corporation,
Appellant

---

and Consolidated Case No. 87-7219

BEFORE: Wald, Chief Judge; Mikva, Edwards, Ruth B. Ginsburg, Silberman, Buckley, Williams, D. H. Ginsburg, Sentelle and Thomas, Circuit Judges

ORDER

Appellees' Suggestion For Rehearing *En Banc* has been circulated to the full Court. No member of the Court requested the taking of a vote thereon. Upon consideration of the foregoing it is

ORDERED, by the Court *en banc*, that the suggestion is denied.

Per Curiam
FOR THE COURT:
CONSTANCE L. DUPRE, CLERK

BY: Robert A. Bonner
Deputy Clerk

Chief Judge Wald did not participate in this matter.

APPENDIX D

ADVISORY COMMITTEE'S NOTE ON FEDERAL RULE OF EVIDENCE 703

Facts or data upon which expert opinions are based may, under the rule, be derived from three possible sources. The first is the firsthand observation of the witness, with opinions based thereon traditionally allowed. A treating physician affords an example. Rheingold, The Basis of Medical Testimony, 15 Vand.L.Rev. 473, 489 (1962). Whether he must first relate his observations is treated in Rule 705. The second source, presentation at the trial, also reflects existing practice. The technique may be the familiar hypothetical question or having the expert attend the trial and hear the testimony establishing the facts. Problems of determining what testimony the expert relied upon, when the latter technique is employed and the testimony is in conflict, may be resolved by resort to Rule 705. The third source contemplated by the rule consists of presentation of data to the expert outside of court and other than by his own perception. In this respect the rule is designed to broaden the basis for expert opinions beyond that current in many jurisdictions and to bring the judicial practice into line with the practice of the experts themselves when not in court. Thus a physician in his own practice bases his diagnosis on information from numerous sources and of considerable variety, including statements by patients and relatives, reports and opinions from nurses, technicians and other doctors, hospital records, and X rays. Most of them are admissible in evidence, but only with the expenditure of substantial time in producing and examining various authenticating witnesses. The physician makes life-and-death decisions in reliance upon them. His validation, expertly performed and subject to cross-

examination, ought to suffice for judicial purposes. Rheingold, *supra*, at 531; McCormick § 15. A similar provision is California Evidence Code § 801(b).

The rule also offers a more satisfactory basis for ruling upon the admissibility of public opinion poll evidence. Attention is directed to the validity of the techniques employed rather than to relatively fruitless inquiries whether hearsay is involved. See Judge Feinberg's careful analysis in *Zippo Mfg. Co.* v. *Rogers Imports, Inc.*, 216 F.Supp. 670 (S.D.N.Y. 1963) See also Blum et al., The Art of Opinion Research: A Lawyer's Appraisal of an Emerging Service, 24 U.Chi.L.Rev. 1 (1956); Bonynge, Trademark Surveys and Techniques and Their Use in Litigation, 48 A.B.A.J. 329 (1962); Zeisel, The Uniqueness of Survey Evidence, 45 Cornell L.Q. 322 (1960); Annot., 76 A.L.R.2d 919.

If it be feared that enlargement of permissible data may tend to break down the rules of exclusion unduly, notice should be taken that the rule requires that the facts or data "be of a type reasonably relied upon by experts in the particular field." The language would not warrant admitting in evidence the opinion of an "accidentologist" as to the point of impact in an automobile collision based on statements of bystanders, since this requirement is not satisfied. See Comment, Cal.Law Rev. Comm'n, Recommendation Proposing an Evidence Code 148-150 (1965).

APPENDIX E

TRIAL TRANSCRIPT

United States District Court

FOR THE DISTRICT OF COLUMBIA

SEKOU EALY, et al.	)	
Plaintiffs	)	Courtroom 7
v.	)	Washington, D.C.
RICHARDSON-MERRELL, INC.	)	Civil Action Number
Defendant	)	83-3504

Before: Honorable June L. Green

— — — — — —

Reported by: Bonnie L. Gahagan

Dawn Copeland
Official Reporter
Phone (202) 535-3397
Room 4806-B, U.S. Courthouse
3rd and Constitution Avenue, N.W.
Washington, D.C. 20001

SELECTED TRIAL TESTIMONY CONCERNING THE TYPES OF FACTS AND DATA ROUTINELY RELIED UPON BY SCIENTISTS IN FORMING OPINIONS OR INFERENCES ABOUT THE CONNECTION BETWEEN DRUGS AND BIRTH DEFECTS

Expert Witnesses for Plaintiffs:

DR. STUART NEWMAN, Professor of Anatomy, N.Y. Medical College; Ph.D. in Chemical Physics, University of Chicago; specialist in developmental biology testifying that animal studies are routinely relied on in examining the causes of birth defects.

Direct by Plaintiffs' Counsel (Tr. 197):

Q: Is that the way it is generally and reasonably done in the field to understand what has happened with the lower animals so you can understand what is going on with man?

A: Yes, this is almost invariably how it is done, particularly when you study embryos. It is not considered ethical to do experiments on human embryos and there are prohibitions against it, and, therefore, scientists study other animals than humans, and compare those animals and apply the information to understanding the human development.

Direct by Plaintiffs' Counsel (Tr. 203):

Q: Are *in vitro* studies generally and reasonably relied upon by developmental biologists, first of all, to try to determine how the body develops?

A: Yes, *in vitro* studies are really the most modern science that is going on now. When people are asking fundamental questions of how parts of the body work, this is really the forefront of studying these things, *in vitro* studies.

* * *

DR. ADRIAN GROSS, V.D.M., Senior Science Advisor, EPA; previously Chief of the Toxicology Branch of the EPA and Chief of Pathology at the FDA — testifying that toxicity testing methods are generally relied upon in determining associations between drugs and various types of disorders, including birth defects.

Direct by Plaintiffs' Counsel (Tr. 817-18):

Q: [Are] the techniques that you utilized in these particular studies the same techniques that are generally and reasonably relied upon to help determine whether or not there is an association between a drug or a birth defect or a carcinogen or anything else that affects the body?

A: Yes, the answer is yes to your question. The method of analysis of the results of any multidose level, no matter what it is, whether it is a study on birth defects, whether it is a study on cancer, whether it is a study on cataracts, whether it is a study on how many animals manifest nervous disorders, whatever, as long as the study was done at several different dose levels, there is this same method of analysis. One looks for trends, and I explained why that is, because if one sees a trend, a significant trend, one then draws a conclusion that the agent on test is associated with or has caused this.

So the method of analysis is common to any toxicity test regardless of what the object of the test is, whether it is birth defects or anything else.

* * *

DR. ALAN KIMBELL DONE, former Professor of Pediatrics and Pharmacology, Wayne State University School of Medicine; former Special Assistant to the Director (for Pediatric Pharmacology), Bureau of Drugs, FDA; specialist in pediatrics,clinical pharmacology and toxicology — testifying about the various types of studies that are generally relied upon to determine whether or not a drug is a teratogen.

Direct by Plaintiffs' Counsel (1207-08):

Q: In giving us that opinion, doctor, are you relying on data that would be generally and reasonably relied upon by those who would usually try to make determinations as to whether or not a drug is a teratogen?

A: Yes.

Q: Scientific evidence, that would generally be relied upon?

A: Yes.

Q: What is that opinion?

A: That it is more likely than not that the drug [Bendectin] was teratogenic on the basis of that information.

Q: Now, doctor, I ask you, what are you relying upon.

A: The evidence that you defined which included the animal data, the human observations, the information about antihistamines generally, and the — well, I think at that point, by '78, that would be all I would need.

Direct by Plaintiffs' Counsel (Tr. 1405-06):

Q: Doctor, a couple of times I believe you indicated in response to some of Mr. Austrian's questions that you need — two human studies that show us a statistically significant association in order to conclude that there is a teratogenic effect, something to that effect? Do you recall that kind of testimony?

A: Yes.

Q: Does that apply, sir, if you have animal studies, knowledge about the pharmacological aspects of a drug and *in vitro* studies?

A: No.

Q: Why not?

A: Well, if all you had was the human data, you want replication of whatever data you have. You would have to have at least two by definition of replication. If you have a

good deal of evidence as is the case here from these other sources, it requires less reliance than on human data, you still want replication of what you have, but that was the case here and that has been done.

* * *

DR. JOHANNES B. THIERSCH, specialist in pathology and pharmacology; former Professor of Clinical Pharmacology at the University of Washington — testifying by deposition that the chemical and physiological characteristics of a drug are significant in analyzing teratogenicity.

Direct by Plaintiffs' Counsel (Tr. 1596):

Q: Doctor, would one also consider the nature of the drug and nature of the animal experiments that had previously been conducted?

. . . .

A: Naturally, the chemical composition and its physiological activity is a decisive factor.

Q: In what way, doctor?

A: We know today that certain molecules are implicated in teratogenic action and we know that other substances of great physiological activity might interfere with the internal metabolism of a developing fetus. Therefore, they are of great interest and of importance.

* * *

DR. SHANNA SWAN, Chief of the Health Assessment and Surveillance Unit of the Epidemiological Studies and Surveillance Section of the California Department of Health Services; Senior Biostatistician in the California state health department; Lecturer in Biostatistics and Epidemiology, University of California — testifying that it is not accepted practice to make determinations regarding teratogenicity based solely on epidemiological data.

Direct by Plaintiffs' Counsel (Tr. 3553-55):

Q: Now, do you yourself do *in vitro* studies or animal studies or work with pharmacology of drugs?

A: No.

Q: Are you aware of their relationships to determining whether or not a drug is a teratogen?

A: Yes.

Q: What is the relationship from the epidemiological standpoint?

A: We work with people in those fields in making the analysis of whether an observed statistical association is causal, and to do that we have employed, for example, in the state toxicologists, biochemists, animal researchers and when we have a problem, we meet and we talk about that and get everybody's input.

Q: Are decisions generally and usually made based solely on epidemiological data as to teratogenicity issues?

A: I am inclined to say never.

Q: Never?

A: Yes. I can't think of any situation where you would only rely on epidemiology. Maybe in an extreme example, but not in the course of my work.

Q: What do you mean by an extreme example? What are you talking about? I don't want a name of anything, but what do you mean by an extreme example?

A: Where the epidemiology was so impelling in and of itself that we would feel without taking the time to collect additional data, it was necessary to take an action in the interest of public health.

Q: Are decisions made that there is not an association between an exogenous substance such as a drug and a defect, are such decisions made solely on epidemiological data?

A: Again, I would have to say almost never, that you have to consider — you would have to have such an enormously precise and powerful epidemiological study to do that to be sure that nothing was going on that I can't imagine that happening.

Q: Is that a view that is generally and reasonably shared by those of you who work in the field of epidemiology full time?

A: I believe that is the commonly held view by epidemiologists.

* * *

Expert Witnesses for Defendant:

DR. MARGOT VAN ALLEN, pediatrician — testifying on the importance of animal data in the study of biological mechanisms.

Direct by Defense Counsel (Tr. 2159-60):

Q: Now, the first question is in view of the human epidemiological studies that you have seen, of what use is the animal studies concerning Bendectin?

A: Well, I think the animal studies for me are important to look at in terms of mechanism of a specific mechanism of damage of the embryo or fetus could be found, I was unable to find any suggested mechanism in those animal studies.

* * *

DR. DAVID ARCHER, obstetrician and gynecologist, — testifying on the fact that certain evidence in support of the defense fails to take account non-epidemiological data.

Redirect by Plaintiffs' Counsel (Tr. 2372-73):

Q: It says here that the committee [FDA Advisory Committee] concluded on the basis of existing epidemiological data,

is that true? You make your conclusions based on epidemiological data?

A: I think that was one aspect of the conclusions.

Q: Doctor, if you want to take a look at it, I think you will find here not one word about animal studies, not one word about *in vitro* studies, not one word about pharmacological data; is that true?

A: Yes, that is true. The reason for that is, I believe, that the epidemiologic studies are the most accurate in terms of what is happening in humans.

* * *

DR. JAMES NEWBERNE, Vice-President of Drug Safety Assessment, Merrell Dow Pharmaceuticals; veterinary pathologist; former head of Merrell Dow's animal teratology testing — testifying about his reliance on animal data in assessing whether Bendectin is safe for human consumption.

Cross by Plaintiffs' Counsel (Tr. 2703-04):

Q: Okay. Let's look at — do you rely on each of these particular [animal] studies that are listed here . . . to in part draw the inference that Bendectin is safe for human consumption?

A: Yet, the totality of all that data I certainly do rely on.

Q: Speaking of human consumption, do you rely on each of these in part for the proposition that Bendectin will not harm the human fetus?

A: Yes, I don't think there is any evidence in any of those that it would harm the human fetus.

Q: Let me make sure I understand. You do rely on each of these [animal studies] in part to draw an inference that Bendectin will not harm the human fetus?

A: Yes.

DR. JUDITH JONES, internist and pharmacologist — testifying on the importance of human data.

Direct by Defense Counsel (Tr. 3292):

Q: . . . Can you tell me whether with respect to drug experience reports it would be appropriate to include in the labeling a description of drug experience reports?

A: It would not be appropriate to include drug experience reports. They represent suspicions, and particularly in the case of birth defects as suspicions could be misleading because it is recognized and this drug which is indicated in pregnancy that there are somewhere between 3 and 5 percent of birth defects that would occur in any 100 pregnancies, for example, three to five birth defects would be seen independent of the drug, so it would be quite misleading to include that information, particularly when epidemiologic studies are available.

Q: Why do you say particularly when epidemiologic studies are available?

A: Well, epidemiologic studies represent the best source of information as to whether or not birth defects are associated with the drug.